
Overdosing on Authority: Negative Side Effects of the FDA’s Proposal for Generic Label Changes May Include Increased Costs and Liabilities

“The risk reasonably to be perceived defines the duty to be obeyed, and risk imports relation; it is risk to another or to others within the range of apprehension.”¹

I. INTRODUCTION

A generic drug is both pharmaceutically equivalent and bioequivalent to its brand-name counterpart.² A variance can, however, exist between the inactive ingredients of the respective drugs.³ Although the two drugs are not required to be identical, their warning labels must be exactly the same.⁴ It is the brand-name manufacturer’s responsibility to ensure that the warning labels are both accurate and adequate, and the generic manufacturer’s corresponding duty to maintain an identical drug label.⁵ This “duty of sameness” prohibits generic drug manufacturers from making unilateral changes to their warning labels.⁶

Despite generic manufacturers’ forced reliance on brand-name warning labels, brand-name manufacturers are immune from liability for failure-to-warn or negligence claims arising from generic drugs.⁷ In a majority of jurisdictions—as long as the drug that caused the injury was generic—brand-name manufacturers escaped negative judgments, even though they played an

1. Palsgraf v. Long Island R.R., 162 N.E. 99, 100 (N.Y. 1928).

2. See 21 U.S.C. § 355(j)(2)(A)(iii)-(iv) (2012) (describing requirements for generic manufacturers’ abbreviated approval of new drug applications); see also *Facts About Generic Drugs*, U.S. FOOD AND DRUG ADMIN., <http://www.fda.gov/drugs/resourcesforyou/consumers/buyingusingmedicinesafely/understandinggenericdrugs/ucm167991.htm> (last updated Sept. 9, 2012) [<http://perma.cc/7T9P-5FKB>] (explaining generic drugs must meet same specifications and quality standards as brand-name drugs).

3. See 21 C.F.R. § 320.1(c) (2009) (defining pharmaceutical equivalence as drug with identical dosage and identical amount of same active ingredient).

4. See *In re Darvocet*, 756 F.3d 917, 923 (6th Cir. 2014) (outlining generic manufacturers’ postmarket “duty of sameness”).

5. See, e.g., 21 U.S.C. § 355(j)(2)(A)(v) (2012) (indicating application for generic drug must contain same label approved for brand-name drug); § 355(j)(4)(G) (explaining acceptance of generic drug application unless insufficient similarity to brand-name drug label); 21 C.F.R. § 314.127(a)(7) (2015) (stating FDA’s refusal of generic drug application stems from labels differing from brand-name labels).

6. See *Dolin v. SmithKline Beecham Corp.*, 62 F. Supp. 3d 705, 711 (N.D. Ill. 2014) (noting Hatch-Waxman Act prohibits generic manufacturers changing warning labels independent of brand-name manufacturers).

7. See *Fisher v. Pelstring*, No. 4:09-cv-00252-TLW, 2010 WL 2998474, at *8 (D.S.C. July 28, 2010) (dismissing brand-name manufacturers from negligence suit because they owed no duty to plaintiffs).

integral role in the initial development of the drug and its warning label.⁸ On an issue of first impression, however, the California Court of Appeals in *Conte v. Wyeth, Inc.*⁹ rejected this traditional view and held that a brand-name manufacturer's duty to warn extends to patients whose prescriptions are filled with the generic version of the drug.¹⁰ Following the decision, three other courts adopted this minority position that brand-name manufacturers can be liable for injuries caused by the generic version of their drug.¹¹

On November 13, 2013, the Food and Drug Administration (FDA) proposed a new rule that would make it nearly impossible for courts to follow that minority view.¹² The new rule would allow generic drug manufacturers to update warning labels without waiting for the brand-name manufacturer to make changes.¹³ This change in policy will have widespread consequences, both positive and negative, for consumers and manufacturers alike, including quicker safety updates for pharmaceuticals.¹⁴ In November 2014, the FDA announced that it was delaying the finalized rule, which was to be published in December 2014, until the fall of 2015; by November 2015, instead of publishing the finalized rule, the FDA again delayed and stated it plans on issuing the final rule by July 2016.¹⁵

8. See, e.g., *Foster v. Am. Home Prods. Corp.*, 29 F.3d 165, 167 (4th Cir. 1994) (holding brand-name manufacturer cannot be liable for injuries resulting from another's drug); *Baymiller v. Ranbaxy Pharm., Inc.*, 894 F. Supp. 2d 1302, 1311 (D. Nev. 2012) (acknowledging brand-name manufacturer owes no duty to warn consumer ingesting generic version); *Finnicum v. Wyeth, Inc.*, 708 F. Supp. 2d 616, 621 (E.D. Tex. 2010) (holding brand-name manufacturer not required to warn about risks related to another manufacturer's drug); *Huck v. Wyeth, Inc.*, 850 N.W.2d 353, 380 (Iowa 2014) (holding brand-name manufacturers owe no duty to consumers using generic drug).

9. 85 Cal. Rptr. 3d 299 (Ct. App. 2008).

10. See *id.* at 320-21 (focusing on foreseeability prescription filled with generic version). Brand-name manufacturers cannot be held strictly liable because they did not manufacture the drug that caused the injury. See Anthony L. Martin, Jr., *California Dreamin'? Generic Drug Users Can Sue Brand Name Drug Manufacturers*, 77 DEF. COUNS. J. 474, 481 (2010) (explaining *Conte* holding). They could, however, be liable for negligent misrepresentation because brand-name manufacturers should reasonably expect that generic manufacturers and prescribers would rely on the safety information they distributed. See *id.*

11. See *Dolin*, 62 F. Supp. 3d at 712 (explaining brand-name manufacturers' negligence foreseeable because state law mandates using generic version if available); *Kellogg v. Wyeth*, 762 F. Supp. 2d 694, 709 (D. Vt. 2010) (stressing foreseeability because physicians rely on brand-name's risks even if pharmacist fills with generic); *Wyeth, Inc. v. Weeks*, 159 So. 3d 649, 676 (Ala. 2014) (allowing fraud or misrepresentation liability for brand-name manufacturers where generic version caused injury).

12. See Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products, 78 Fed. Reg. 67,985 (proposed Nov. 13, 2013) (to be codified at 21 C.F.R. pts. 314, 610) (proposing new regulations allowing generic manufacturers to change warning labels).

13. See *id.* (outlining major provisions of proposed rule for changing generic warning labels).

14. See *id.* (noting ability of all application holders to update labels improves communication of information to prescribers).

15. See Bronwyn Mixer, *HHS Rule Agenda Includes 340B, FDA Regulations*, BLOOMBERG (Nov. 25, 2015), <http://www.bna.com/hhs-rule-agenda-n57982063988/> [<http://perma.cc/C4YK-M584>] (stating proposal highly criticized and finalized rule continuously pushed back); Ed Silverman, *FDA Delays Final Rule on Allowing Generic Drug Makers To Update Labels*, WALL ST. J. PHARMALOT (Nov. 18, 2014, 8:46 AM), <http://blogs.wsj.com/pharmalot/2014/11/18/fda-delays-final-rule-on-allowing-generic-drug-makers-to-update->

This Note will explore the procedure for introducing new drugs and chronicle changes in manufacturers' postmarket duties.¹⁶ It will also explain the proposed rule for making changes to a drug's warning label.¹⁷ In Part II, this Note will examine how different courts handled liability issues between brand-name and generic drug manufacturers, and it will focus on the recent shift in liability to brand-name manufacturers for injuries caused by generic versions of their drugs.¹⁸ In Part III, this Note will analyze the proposed rule's effects on consumers, prescribing physicians, and drug manufacturers.¹⁹ In conclusion, this Note will provide an overall impression of the proposed rule and further suggest that the FDA not finalize this rule as it is currently proposed.²⁰

II. HISTORY

A. *Process of Marketing New Drugs in Interstate Commerce*

A new pharmaceutical drug cannot be introduced into interstate commerce until the FDA approves its application.²¹ The process for filing a new drug application is cumbersome and extensive.²² In addition to filing the application, the applicant must also file the patent number and expiration date of any other patents claiming the drug or a method for using it.²³ Within 180 days from the application's filing, the Secretary shall either approve the new

labels/ [<http://perma.cc/NQ6Y-YM6P>] (citing controversial nature of policy as reason for delay in finalized rule); *see also* Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products, 78 Fed. Reg. at 67,985 (indicating final rule likely in September 2015).

16. *See infra* Parts II.A-C.

17. *See infra* Part II.D.

18. *See infra* Parts II.E-F.

19. *See infra* Part III.

20. *See infra* Part IV.

21. *See* 21 U.S.C. § 355(a) (2012) (stating necessity of approving application); *see also In re Darvocet*, 756 F.3d 917, 922 (6th Cir. 2014) (emphasizing drug manufacturers must obtain FDA approval before marketing in interstate commerce).

22. *See* 21 U.S.C. § 355(b)(1) (2012) (listing seven requirements for new drug application); *see also In re Darvocet*, 756 F.3d at 922 (describing process and requirements for submitting new drug application); 21 C.F.R. § 314.50(d) (2008) (detailing required technical sections, including chemistry, nonclinical pharmacology and toxicology, and human pharmacokinetics and bioavailability). The application must include full reports of investigations into whether the drug is safe and effective for use. *See* 21 U.S.C. § 355(b)(1) (2012). A full statement of the drug's composition and a full description of the methods, facilities, and controls used for manufacturing, processing, and packing the drug must also be included. *See id.* Additionally, the application must contain samples of the drug and articles used as components if the Secretary of Health and Human Services requests them. *See id.*; *see also* 21 U.S.C. § 321(d) (2012) (defining "Secretary"). The application must also include a sample of the proposed labeling and any other assessments required under Section § 355(c). *See* 21 U.S.C. § 355(b)(1) (2012); *see also* § 355(c) (2012) (declaring application must also include tests concerning pediatric use).

23. *See* 21 U.S.C. § 355(b)(1) (2012) (requiring filing of expiration of all patents for which patent infringement claims possibly asserted).

drug or give the applicant notice of a hearing.²⁴ After a hearing, an application can be rejected for a variety of reasons, including insufficient testing on drug safety or results showing the drug to be unsafe.²⁵

The two major concerns with approving new drugs into the market are safety and efficacy.²⁶ It is unlikely any drug is completely safe for all people under all circumstances; thus the safety assessment of new drugs requires a delicate balancing test.²⁷ A new drug is deemed unsafe if its potential for death or physical injury outweighs its therapeutic benefit.²⁸ The FDA can similarly refuse to approve a new drug if there is no substantial evidence that the drug is effective for its intended use.²⁹

B. FDA Prescribes the Hatch-Waxman Act To Create a Cheaper Drug Market

Traditionally, all new drugs followed the same tedious application process, regardless of whether it was a generic or a brand-name drug.³⁰ In response, Congress passed the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act).³¹ The Hatch-Waxman Act was a compromise between brand-name drug manufacturers and generic drug manufacturers that sought to induce brand-name manufacturers to invest in research and development for new drugs while also bringing cheaper, generic versions of

24. See § 355(c)(1) (explaining 180-day window for Secretary's decision unless Secretary and applicant agreed upon extension).

25. See § 355(d) (providing reasons for rejection of application). The application will be rejected if: the investigation lacks adequate tests using all reasonable methods to determine the drug's safety under recommended conditions; the test results show the drug is unsafe under those conditions or fails to show the drug's safety under those conditions; the methods, facilities, and controls used for manufacturing, processing, and packing the drug are "inadequate to preserve its identity, strength, quality, and purity"; the Secretary lacks enough information to determine the drug's safety; the application lacks "substantial evidence" that the drug will have the claimed effect under the recommended conditions and uses; the application omits the required patent information; or the labeling is "false or misleading." *Id.*

26. See 21 U.S.C. § 321(p) (2012) (focusing definition of "new drug" on safety and effectiveness); see also *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 609 (1973) (highlighting emphasis procedures put on new drug's efficacy). But see Jonathan J. Darrow, *Pharmaceutical Efficacy: The Illusory Legal Standard*, 70 WASH. & LEE L. REV. 2073, 2075-76 (2013) (criticizing FDA's efficacy standards).

27. See *United States v. Rutherford*, 442 U.S. 544, 555-56 (1979) (declaring drugs generally safe if predicted therapeutic benefit justifies risk of use).

28. See *id.* (discussing safety determination for drugs for terminally ill patients).

29. See 21 U.S.C. § 355(d) (2012) (defining substantial evidence as "evidence consisting of adequate and well-controlled investigations"). Substantial evidence includes clinical investigations by qualified experts who evaluate drug effectiveness based on whether they can conclude the drug will have its stated effect. See *id.*

30. See *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2574 (2011) (describing drug-approval procedures prior to 1984); *In re Darvocet*, 756 F.3d 917, 922-23 (6th Cir. 2014) (explaining same process used for generic drugs because they represent "copies" of previously approved drugs).

31. See Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended in scattered sections of 21 U.S.C.) (passing Hatch-Waxman Act); see also *In re Darvocet*, 756 F.3d at 922 (stating Congress passed Hatch-Waxman Act due to "onerous" process of submitting applications); Colleen Kelly, *The Balance Between Innovation and Competition: The Hatch-Waxman Act, the 2003 Amendments, and Beyond*, 66 FOOD & DRUG L.J. 417, 420-21 (2011) (claiming Hatch-Waxman Act solved years of problems regarding approval for generic drugs).

those drugs to consumers.³² Congress designed the Hatch-Waxman Act to provide access to more cost-efficient generic drugs by establishing an approval process for all new drugs approved after 1962.³³

The Hatch-Waxman Act allows an applicant to file an abbreviated application for a new generic drug.³⁴ A generic manufacturer can enter the market using this expedited process when the brand-name manufacturer's patent expires.³⁵ The abbreviated application has fewer extensive requirements, making the application process easier and faster for generic drugs to enter the market.³⁶ Not only did the Hatch-Waxman Act benefit generic drug manufacturers, but it also achieved its desired balance by providing innovative pharmaceutical companies with the ability to receive a patent extension on their brand-name drugs.³⁷

The Hatch-Waxman Act's success is unprecedented in the pharmaceutical industry.³⁸ It prompted an eighty-six percent generic substitution rate by 2014,

32. See *Abbott Labs. v. Young*, 920 F.2d 984, 991 (D.C. Cir. 1990) (Edwards, J., dissenting) (categorizing Hatch-Waxman Act as "product of compromise"); see also Kelly, *supra* note 31, at 420-21 (indicating Hatch-Waxman Act intended to accommodate conflicting interests of innovators and generic drug manufacturers); Janet A. Gongola, Note, *Prescriptions for Change: The Hatch-Waxman Act and New Legislation To Increase the Availability of Generic Drugs to Consumers*, 36 IND. L. REV. 787, 787 (2003) (claiming Hatch-Waxman Act sought to balance interests of innovative manufacturers and generic drug manufacturers).

33. See H.R. REP. NO. 98-857, pt. 1, at 14 (1984); see also *Dolin v. SmithKline Beecham Corp.*, 62 F. Supp. 3d 705, 711 (N.D. Ill. 2014) (stating Hatch-Waxman Act passed to make more generic drugs available safely and inexpensively).

34. See *In re Darvocet*, 756 F.3d at 923 (explaining generic drug possibly approved using abbreviated new drug application).

35. See *Dolin*, 62 F. Supp. 3d at 711 (describing process for filing abbreviated application for new generic drug).

36. See 21 U.S.C. § 355(j)(2)(A)(i)-(viii) (2012) (listing requirements for abbreviated application for new drug). The abbreviated application must include information showing: the proposed use and labeling were previously approved for a "listed drug"; the active ingredients of the new drug are the same as in the listed drug; administration, dosage form, and strength are the same for the new drug, as with the listed drug; the new drug is bioequivalent to the listed drug; the labeling proposed for the new drug is the same as labeling that is approved for the listed drug; and a certification regarding patents for the listed drug. *Id.*

37. See 35 U.S.C. § 156(a) (2012) (granting extension for patent claiming product, method of using product, or method of manufacturing product); see also *Merck & Co. v. Kessler*, 80 F.3d 1543, 1546-47 (Fed. Cir. 1996) (noting Hatch-Waxman Act expedited generic drugs in exchange for extending patents of approved drugs). The term of the patent will be extended if the term does not expire before an application for extension is submitted; the term was never extended; the patent owner or its agent fulfill the requirements listed; and the patent-protected product underwent a regulatory review period before it was used or marketed. See 35 U.S.C. § 156(a). The period of extension is equivalent to the regulatory review period, which is the delay the approved drug encountered while awaiting FDA approval. See *id.* § 156(c); *Merck & Co.*, 80 F.3d at 1547. That period is limited to two years for patents issued before the passage of the Hatch-Waxman Act and five years for patents issued after its passage. See § 156(g)(6)(A)-(C). The entire term of the patent, including the extension, cannot exceed fourteen years. See § 156(c)(3).

38. See Kyle Sampson & Sheldon Bradshaw, *FDA's Proposed Generic Drug Labeling Rule*, UPDATE, July/Aug. 2014, at 6, http://www.hunton.com/files/Publication/48128f22-c82c-4dd5-876d-079cb7dbe1cc/Presentation/PublicationAttachment/b1480d80-25ef-4bb5-a0c3-12ec1547e5b9/FDAs_Proposed_Generic_Drug_Labeling_Rule.pdf [<http://perma.cc/P8KD-SKHQ>] (claiming Hatch-Waxman Act created modern generic drug industry). Due to the Hatch-Waxman Act, the United States developed the most successful generic drug

which consequently saved consumers and the healthcare system billions of dollars.³⁹ The Act also benefited the public by stimulating new drug innovation.⁴⁰ Since 2000, brand-name drug manufacturers invested over \$500 billion in research and development for new drugs.⁴¹ This increased funding for new drug development created hundreds of new drugs that will help patients live higher quality lives, and, as of 2014, 3400 more drugs are currently in development.⁴² The Hatch-Waxman Act is responsible for creating the system in which more than ninety percent of all approved, brand-name drugs have generic alternatives that allow patients to improve their standard of living in a safe and affordable manner.⁴³

C. Post-Market Duties: Differing Treatments for Brand-Name and Generic Drug Manufacturers

Once a new drug application or an abbreviated new drug application is approved, the manufacturers cannot make any major changes to the drug's formulation without the FDA's approval.⁴⁴ Both brand-name and generic drug manufacturers must continue to monitor their drug and review any reports they receive of an adverse drug experience.⁴⁵ Serious adverse drug experiences must be reported to the FDA almost immediately, whereas most other, less serious adverse experiences need only be reported one to four times per year.⁴⁶

industry in the world and is the leader in new drug innovation. See GENERIC PHARM. ASS'N, HATCH-WAXMAN: DRIVING ACCESS, SAVINGS & INNOVATION 3 (2014), http://www.gphaonline.org/media/cms/Hatch_Waxman_Driving_Access_Savings_and_Innovation.pdf [<http://perma.cc/7C5K-PSMT>].

39. See GENERIC PHARM. ASS'N, *supra* note 38, at 1-2 (providing generic substitution rates since passage of Hatch-Waxman Act).

40. See *id.* at 3 (explaining Hatch-Waxman Act provides enticing incentives for brand-name manufacturers to develop new drugs).

41. See *id.* at 4 (stating FDA approved 300 new drugs between 2004 and 2014).

42. See *id.* (acknowledging health benefits of new drugs, including cancer treatment and reduction of cardiovascular problems); see also *Medicines in the Pipeline: Explore the Drug Discovery Pipeline*, PHARM. RES. AND MANUFACTURERS AM. (2014), <http://www.phrma.org/pipeline> [<http://perma.cc/2C5N-KM39>] (declaring potential for new treatments stemming from increased research and development of drugs "unprecedented").

43. See GENERIC PHARM. ASS'N, *supra* note 38, at 1 (elucidating importance of Hatch-Waxman Act on healthcare system).

44. See *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2471 (2013) (stating manufacturer prohibited from making major changes to formulation of drug); 21 C.F.R. § 314.70(a) (2015) (forbidding applicant from making changes not provided for in approved application without first notifying FDA). Changes require further approval if they have potentially adverse effects on the "identity, strength, quality, purity, or potency of the drug product." § 314.70(b)(1). This includes any changes to the drug substance or in the production process—like quality controls, equipment, or facilities. See *id.*

45. See *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2584 (2011) (explaining drug manufacturers responsible for monitoring safety because have best access to information). An adverse drug experience includes an adverse use of a drug in a professional practice, or an adverse use resulting from an accidental or intentional drug overdose, from drug abuse, from drug withdrawal, or from any failure of anticipated pharmacological action. See 21 C.F.R. § 314.80(a) (2015).

46. See § 314.80(c) (providing manufacturers must report "serious and unexpected" adverse effects

Although brand-name and generic drug manufacturers' monitoring responsibilities are the same, the two manufacturers have different labeling duties.⁴⁷ Brand-name drug manufacturers are responsible for the accuracy and the adequacy of the drug's warning label.⁴⁸ Generic drug manufacturers instead have a "duty of sameness," which requires that the generic drug label be identical to the brand-name drug's label.⁴⁹ As a result of that duty, generic drug manufacturers are prohibited from making unilateral changes to any warning labels for any of their drugs.⁵⁰ Despite this inability to unilaterally change their drug labels, if generic drug manufacturers think their warning labels are inadequate, they must provide the FDA with any information they have about the new risks to ensure the drug's safety for consumers.⁵¹

D. FDA Proposed Regulation Speeds Dissemination of Information

On November 13, 2013, the FDA proposed a new rule that would allow generic drug manufacturers to revise their drug label and temporarily distribute a label that is different from the listed drug's warning label.⁵² The FDA will

within fifteen days); *see also* *PLIVA, Inc.*, 131 S. Ct. at 2584 (describing process for both brand-name and generic manufacturers to report negative effects to FDA); *Barnhill v. Teva Pharm. USA, Inc.*, 819 F. Supp. 2d 1254, 1263 (S.D. Ala. 2011) (refusing to extend duty of manufacturer to also monitor adverse experiences of other drug manufacturers).

47. *See* *PLIVA, Inc.*, 131 S. Ct. at 2574 (explaining brand-name manufacturers responsible for accuracy and adequacy, while generic manufacturers responsible for consistency); *see also* *In re Darvocet*, 756 F.3d 917, 923 (6th Cir. 2014) (stating brand-name manufacturers maintain accuracy and adequacy, and generic manufacturers must maintain same label).

48. *See* 21 U.S.C. § 355(b)(1) (2012) (requiring application for new drug to contain proposed labeling); *PLIVA, Inc.*, 131 S. Ct. at 2574 (maintaining brand-name drug manufacturers responsible for accuracy of drug's label); *Wyeth v. Levine*, 555 U.S. 555, 570-71 (2009) (deeming drug manufacturer, not FDA, responsible for label content).

49. *See* *In re Darvocet*, 756 F.3d at 923 (characterizing generic manufacturers' duty to ensure label same as brand-name's as "duty of sameness"); *see also* *Gardley-Starks v. Pfizer, Inc.*, 917 F. Supp. 2d 597, 605 (N.D. Miss. 2013) (stating all generic-drug-manufacturer-issued labels must be same as brand-name drug); Caitlin Sawyer, Note, *Duty of "Sameness"?: Bartlett Preserves Generic Drug Consumers' Design Defect Claims*, 54 B.C. L. REV. E-SUPPLEMENT 1, 4 (2013) (explaining generic manufacturers develop "copycat drugs" and must show drug has same label).

50. *See* *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2471 (2013) (emphasizing generic drug manufacturers prohibited from unilaterally changing drug's label); 21 C.F.R. § 314.150(b)(10) (2015) (allowing withdrawal of approval for generic drug if labeling no longer consistent with listed drug). Thus, generic drug manufacturers can only change their labels to adhere to their duty of sameness when the brand-name label is updated or if the FDA instructs them to do so. *See* *Bell v. Pfizer, Inc.*, 716 F.3d 1087, 1094 (8th Cir. 2013).

51. *See* *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2585 (2011) (clarifying prohibition on changes requires manufacturers to act if label deemed inadequate). The current FDA regulation requires revising the label when the manufacturer learns of "reasonable evidence of an association of a serious hazard with a drug." 21 C.F.R. § 201.80(e) (2015). Therefore, when generic drug manufacturers have information that warrants additional warnings for their drug, they have a duty to try to revise the label and provide the FDA with that information. *See* *PLIVA, Inc.*, 131 S. Ct. at 2585.

52. *See* Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products, 78 Fed. Reg. 67,985, 67,989 (proposed Nov. 13, 2013) (to be codified at 21 C.F.R. pts. 314, 610) (proposing abbreviated new drug application holders to submit changes being effected, or CBE-o, supplement).

require the generic drug manufacturer to send notice of both the proposed labeling changes and the information supporting those changes to the brand-name manufacturer when it submits the CBE-o supplement.⁵³ Perceiving healthcare providers as unlikely to review labels for every generic drug, the FDA also proposed creating a website where the FDA would promptly post information about proposed warning label changes while it reviews the CBE-o supplement.⁵⁴ The proposed website would be accessible to healthcare providers, as well as the general public, and would provide information about CBE-o supplements in review, including: “[t]he active ingredient, the trade name (if any), the application holder, the date on which the supplement was submitted, a description of the proposed labeling change and source of the information supporting the proposed labeling change . . . , and the status of the pending CBE-o supplement.”⁵⁵ The proposed amendment addresses safety concerns about unilateral label changes for generic drugs by permitting the FDA to send a request letter notifying the brand-name manufacturer of the new safety information.⁵⁶ The FDA would then evaluate the proposed label change for the generic drug and approve it for both the generic drug’s label and the corresponding brand-name drug’s label.⁵⁷

These regulations are intended to improve and simplify the process for application holders to change the labeling of an approved drug to provide newly acquired information before the FDA reviews the label change through a CBE-o supplement.⁵⁸ Additionally, by permitting generic drug manufacturers to update the safety information on their drugs’ labels, the proposed rule would significantly accelerate distributing new information about generic drug safety

The amendment would apply equally to generic drug manufacturers holding an approved abbreviated new drug application and brand-name manufacturers with an approved new drug application. *See id.* A drug manufacturer files a CBE-o supplement only to indicate newly acquired drug information. *See id.* at 67,987. The supplemental application serves to add or strengthen a warning only if there is sufficient evidence that the approved drug caused the adverse reaction. *See id.*

53. *See id.* at 67,986 (explaining procedure ensures brand-name manufacturers promptly advised of new information for label changes).

54. *See id.* at 67,989 (acknowledging safety concerns in allowing therapeutically equivalent drugs to temporarily have different warning labels).

55. *Id.*

56. *See* Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products, 78 Fed. Reg. at 67,992 (proposing FDA send notice if brand-name manufacturer fails to submit conforming label changes).

57. *See* Press Release, U.S. Food and Drug Admin., FDA Takes Action To Speed Safety Information Updates on Generic Drugs (Nov. 8, 2013), <http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm374171.htm> [<http://perma.cc/NS75-RAK9>] (outlining proposed changes to procedure require generic manufacturer wait for brand-name to change label); *see also* Natalie Blazer, *FDA Draws Criticism, Praise on Proposed Generic Drugs Rule*, WEIL PROD. LIAB. MONITOR (Jan. 28, 2014), <http://product-liability.weil.com/pharmaceutical-law/fda-draws-criticism-praise-on-proposed-generic-drugs-rule/> [<http://perma.cc/4WTP-XSU> Y] (explaining FDA decision about labeling would apply to generic and brand-name drugs if approved).

58. *See* Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products, 78 Fed. Reg. 67,985 (proposed Nov. 13, 2013) (to be codified at 21 C.F.R. pts. 314, 610) (amending regulations “to revise and clarify procedures for application holders”).

to healthcare providers and consumers.⁵⁹ The proposal would also solve both preemption concerns regarding state-law-imposed duties while ensuring all drug manufacturers can fulfill their requirement to monitor their drugs' safety information and update their warning labels accordingly.⁶⁰

Reactions to the proposed regulation, however, are overwhelmingly negative.⁶¹ Critics argue the proposal contradicts the Hatch-Waxman Act's inherent purpose because it allows the promotion of chemically identical and bioequivalent drugs with warning labels communicating different safety information.⁶² In addition to confusing prescribers and consumers, this new

59. See Press Release, U.S. Food and Drug Admin., *supra* note 57 (explaining proposal ensures healthcare providers and consumers can access most updated drug information); Kate Traynor, *FDA Defends Generic Drug Labeling Plan*, AM. SOC'Y OF HEALTH-SYS. PHARMACISTS (May 15, 2014), <http://www.ashp.org/menu/News/PharmacyNews/NewsArticle.aspx?id=4049> [<http://perma.cc/GP22-Z3WS>] (highlighting improved communication of safety information if proposal enacted).

60. See *Examining Concerns Regarding FDA's Proposed Changes to Generic Drug Labeling*, Hearing on 78 Fed. Reg. 67,985 Before the H. Subcomm. on Health, Comm. on Energy and Commerce, 113th Cong. (2014) (statement of Janet Woodcock, Director, Center for Drug Evaluation and Research), <http://www.fda.gov/NewsEvents/Testimony/ucm389606.htm> [<http://perma.cc/9GUA-ZDTC>] [hereinafter Woodcock Statement] (stating proposal ensures accuracy of drug labels and allows manufacturers to communicate new information).

61. See, e.g., ALEX BRILL, MATRIX GLOB. ADVISORS, FDA'S PROPOSED GENERIC DRUG LABELING RULE: AN ECONOMIC ASSESSMENT 3 (Feb. 5, 2014), <http://www.matrixglobaladvisors.com/GenericLabelingRule.pdf> [<http://perma.cc/UEQ8-7YHM>] (highlighting inaccuracies of FDA's analysis of impact of new rule); Brittany Croom, Note, *Buyer Beware: Mutual Pharmaceutical Co. v. Bartlett Continues To Alter the True Costs and Risks of Generic Drugs*, 15 N.C. J.L. & TECH. ONLINE 1, 29-30 (2014) (outlining proposal's potential positive and negative effects and likelihood it undermines purpose of generic drugs); Letter from Steve Israel & Timothy H. Bishop, Members of Cong., to Margaret A. Hamburg, Comm'r, U.S. Food and Drug Admin. (Aug. 26, 2014), http://www.gphaonline.org/media/cms/Generic_labeling_FDA_2014_08_26.pdf [<http://perma.cc/PW4H-E9WS>] [hereinafter Letter from Israel & Bishop] (stating concerns over generic drug supply and consumer confusion if proposal accepted); Letter from Members of Cong. to Margaret A. Hamburg, Comm'r, U.S. Food and Drug Admin. (Jan. 22, 2014), <http://energycommerce.house.gov/sites/republicans.energycommerce.house.gov/files/letters/20140122FDA.pdf> [<http://perma.cc/VK48-7S9V>] [hereinafter Letter from Members of Cong.] (expressing "grave concerns" about FDA's proposal to change procedure of Hatch-Waxman Act); Letter from Minority Orgs., to Margaret A. Hamburg, Comm'r, U.S. Food and Drug Admin. (Sept. 30, 2014), http://www.gphaonline.org/media/cms/Second_Minority_Org_Letter_to_FDA_09_25_1.pdf [<http://perma.cc/CJ39-LUSU>] [hereinafter Letter from Minority Orgs.] (asking FDA to "fully explore the potential unintended and harmful consequences" of proposed law); Letter from David C. Spangler, Senior Vice President, Consumer Healthcare Prod. Ass'n, to U.S. Food and Drug Admin. (Mar. 11, 2014), <http://www.chpa.org/andalabelingcomments.aspx> [<http://perma.cc/4GZD-FMC6>] [hereinafter Letter from Spangler] (articulating concerns over proposal's effect on over-the-counter drugs). The proposal undercuts the required duty of sameness because it allows generic drug manufacturers to unilaterally change their drug labels by submitting a CBE-o supplement. See Letter from Members of Cong., *supra*.

62. See Press Release, Generic Pharm. Ass'n, GPhA to Cong.: FDA Proposed Rule on Labeling Risks Widespread Confusion, Undermines Hatch-Waxman (Feb. 28, 2014) (on file with author), <http://www.gphaonline.org/gpha-media/press/gpha-to-congress-fda-proposed-rule-on-labeling-risks-widespread-confusion-undermines-hatch-waxman> [<http://perma.cc/A97Y-CZDP>] [hereinafter GPhA to Cong.] (stating proposal undermines "cornerstone of the success of generic medicines in the last thirty years"); Letter from Members of Cong., *supra* note 61 (addressing likely confusion from healthcare providers and consumers if different labels for same drug); see also GENERIC PHARM. ASS'N, GPHA OVERVIEW AND ASSESSMENT: FOOD AND DRUG ADMINISTRATION'S PROPOSED RULE SUPPLEMENTAL APPLICATIONS PROPOSING LABELING CHANGES FOR APPROVED DRUGS AND BIOLOGICAL PRODUCTS 11 (Jan. 2014), http://www.gphaonline.org/media/cms/GPhA_Labeling_White_Paper_1.29.14_FINAL.pdf [<http://perma.cc/BNJ5-3M4H>] [hereinafter GPHA OVERVIEW AND

proposal may also increase the costs of generic drugs by effectively undercutting the Hatch-Waxman Act's objective and decreasing the amount of cheap, safe alternatives.⁶³ Furthermore, it is unclear whether the FDA even has the authority to implement these new regulations and dramatically, or even illegally, stray from the Hatch-Waxman Act.⁶⁴

E. Preemption Concerns with Failure-To-Warn Claims

The legal system currently places a strong emphasis on whether the drug allegedly causing an injury is a generic or brand-name drug in failure-to-warn claims.⁶⁵ If the lawsuit is brought against a brand-name drug manufacturer, there is no conflict or preemption with the FDA's prior label approval because the manufacturer has the ability to unilaterally change the label.⁶⁶ If, however,

ASSESSMENT] (concluding proposal will create confusion due to inconsistency of generic and brand-name drug labels); FAIRLEIGH DICKINSON UNIV., GENERIC PHARM. ASS'N, HEALTHCARE PROFESSIONALS' PERSPECTIVES: FDA PROPOSED RULE ON GENERIC DRUG LABELING 3 (June 18, 2014), http://www.gphaonline.org/media/cms/FDA_Report_v2_4_FINAL_2_.pdf [<http://perma.cc/98FX-PDUB>] [hereinafter FAIRLEIGH DICKINSON UNIV.] (reporting strong response related to likelihood of confusion among healthcare professionals).

63. See Letter from Members of Cong., *supra* note 61 (warning duplicative testing possible because proposal's failure to alert manufacturer of prior rejected labeling changes); see also Beatrice Skye Resendes, Note, *The Extinct Distinction of Privity: When a Generic Drug Label Fails To Warn, the Drug's Pioneer Should Be Liable as Component Part Supplier of the Warning Label*, 32 T. JEFFERSON L. REV. 95, 113 (2009) (claiming differing warning labels contradicts ability to have lower drug costs). The proposal threatens the balance the Hatch-Waxman Act achieved between encouraging research and making drugs affordable, as it would significantly increase the cost of both generic and brand-name drugs. See Letter from Members of Cong., *supra* note 61. In 2013, generic drugs saved government agencies, consumers, and other insurers \$239 billion. See GENERIC PHARM. ASS'N, GENERIC DRUG SAVINGS IN THE U.S. 1 (6th ed. 2014), http://www.gphaonline.org/media/cms/GPhA_Savings_Report.9.10.14_FINAL.pdf [<http://perma.cc/FE3W-3NQU>]. The proposal exposes generic drug manufacturers to the costly litigation that typically concerns brand-name manufacturers, which would directly correlate to increased drug prices. See SCOTT GOTTLIEB ET AL., PROPOSED FDA GENERIC DRUG REGULATION: HIGHER PRICES, NO PUBLIC HEALTH BENEFIT, AM. ENTERPRISE INST. FOR PUB. POL'Y RES. 2-4 (2014), http://www.aei.org/wp-content/uploads/2014/03/-health-policy-outlook-march-2014_135106617382.pdf [<http://perma.cc/7FY3-HGYZ>] (arguing proposal undercuts major benefits provided by generic drugs).

64. See Alexander Gaffney, *Experts: FDA's Generic Drug Labeling Rule Likely Illegal*, REG. AFF. PROFS. SOC'Y (Nov. 15, 2013), <http://www.raps.org/regulatoryDetail.aspx?id=9655> [<http://perma.cc/X2P4-DFYT>] [hereinafter *Experts*] (outlining legal experts' arguments against legality of FDA's proposal); Alexander Gaffney, *Generic Drug Industry Threatens FDA with Lawsuit Over Drug Labeling Proposal*, REG. AFF. PROFS. SOC'Y (Oct. 7, 2014), <http://www.raps.org/Regulatory-Focus/News/2014/10/07/20497/Generic-Drug-Industry-Threatens-FDA-With-Lawsuit-Over-Drug-Labeling-Proposal/> [<http://perma.cc/5V2K-Q9ZB>] [hereinafter *Generic Drug Industry Threatens FDA*] (detailing issues with FDA's legal authority to pass proposal). If the proposal is finalized, the Generic Pharmaceutical Association (GPhA) promises to bring a lawsuit against the FDA, questioning whether the rule is ultimately legal. See Jeff Overley, *Generics Lobby Threatens Suit Over FDA Warning Labels Plan*, LAW360 (Sept. 23, 2014), <http://www.law360.com/articles/579957/generics-lobby-threatens-suit-over-fda-warning-labels-plan> [<http://perma.cc/HQB5-EB5X>].

65. See *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2581 (2011) (finding preemption despite *Wyeth v. Levine* because involving generic drugs "makes little sense"); Daniel Kazhdan, Note, *Wyeth and PLIVA: The Law of Inadequate Drug Labeling*, 27 BERKELEY TECH. L.J. 893, 893 (2012) (noting Supreme Court's distinction between failure-to-warn claims against brand-name and generic manufacturers).

66. See *Wyeth v. Levine*, 555 U.S. 555, 575 (2009) (stating no preemption because FDA's approval of label not "exclusive means" for drug safety); Kazhdan, *supra* note 65, at 896 (describing majority opinion in

the suit is against a generic drug manufacturer, the Hatch-Waxman Act's prohibition on generic manufacturers' unilateral changes preempts the failure-to-warn claim.⁶⁷ Court access, therefore, depends upon whether the person ingested a brand-name drug or a generic drug, rather than upon the strength of the case itself.⁶⁸ By allowing generic drug manufacturers to independently alter their labels, the proposed regulations may eliminate preemption concerns over these failure-to-warn claims against generic drugs.⁶⁹

F. Overview of Shift in Liability from Generic Manufacturers to Brand-Name Manufacturers

Originally, most jurisdictions found brand-name drug manufacturers immune from liability for any injuries caused by the generic version of their drug.⁷⁰ Starting in 2008, however, a minority view emerged that shifted

Wyeth v. Levine). The reasoning behind the *Wyeth v. Levine* decision rests on the argument that the FDA alone cannot effectively monitor warning labels, so state tort claims are necessary as an alternative means of enforcement. See Kazhdan, *supra* note 65, at 901. Due to limited resources and manufacturers' greater access to information about their drugs, the FDA "traditionally regarded state law as a complementary form of drug regulation." *Wyeth*, 555 U.S. at 578. Allowing failure-to-warn claims incentivizes manufacturers to disclose safety risks associated with their drugs quickly because the manufacturers themselves, rather than the FDA, are responsible for their drugs' warning labels. See *id.* at 579.

67. See Kazhdan, *supra* note 65, at 900 (explaining *PLIVA* held failure-to-warn suits against generic manufacturers as preempted). The Court in *PLIVA* held that if the generic manufacturers independently changed their labels to satisfy the duty under a state's law, they would incidentally violate the federal law's duty of sameness. See 131 S. Ct. at 2578. It is impossible for a manufacturer to comply with both laws simultaneously, so the federal Hatch-Waxman Act preempts state law. See *id.* A generic manufacturer is thus prohibited from unilaterally changing its warning label, despite any state law requirements to the contrary. See *id.* The ruling in *PLIVA* implies both that the FDA's approval of a drug's warning label is sufficient to maintain drug safety and that any failure-to-warn or inadequate labeling tort claims would be unnecessarily repetitive. See Kazhdan, *supra* note 65, at 901.

68. See Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products, 78 Fed. Reg. 67,985, 67,988 (proposed Nov. 13, 2013) (to be codified at 21 C.F.R. pts. 314, 610) (explaining impact of *Wyeth v. Levine* and *PLIVA* decisions on ability to assert legal claims); see also *Proposed Rule from FDA Would Allow Generic Drug Manufacturers To Make Unilateral Changes to Labeling Changes May Affect Federal Preemption of State Tort Law Failure-To-Warn Claims Involving Generics*, 22 No. 10 FDA ENFORCEMENT MANUAL NEWSL. (Thompson Info. Servs.), Dec. 2013, at 3 [hereinafter *Proposed Rule from FDA*] (reiterating access to courts dependent upon manufacturer of ingested drug).

69. See Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products, 78 Fed. Reg. at 67,989 (stressing proposed label regulations may abolish preemption concerns because they ensure generic manufacturers "actively participate").

70. See Greg Ryan, *GSK Can't Escape Suit Over Reed Smith Atty's Suicide*, LAW360 (Mar. 4, 2014, 5:06 PM), <http://www.law360.com/articles/515187/gsk-can-t-escape-suit-over-reed-smith-atty-s-suicide> [<http://perm.a.cc/FLH2-49UZ>] (discussing contradictory ruling in Illinois holding brand-name manufacturer liable for suicide generic version caused); see, e.g., *In re Darvocet*, 756 F.3d 917, 937-38 (6th Cir. 2014) (dismissing claim against brand-name manufacturer because did not manufacture injury-causing product); *Baymiller v. Ranbaxy Pharm., Inc.*, 894 F. Supp. 2d 1302, 1311 (D. Nev. 2012) (holding brand-name manufacturer not liable because did not manufacture or sell injury-causing drug); *Huck v. Wyeth, Inc.*, 850 N.W.2d 353, 380 (Iowa 2014) (rejecting argument considering brand-name manufacturers as "de facto insurers" for generic manufacturers).

liability onto brand-name manufacturers.⁷¹ After the controversial decision in *Conte v. Wyeth*, courts in Alabama, Illinois, and Vermont all ruled against brand-name manufacturers and upheld innovator liability.⁷² The reasoning behind these decisions partially rests on the idea that it is reasonably foreseeable for a prescribing physician to rely upon warnings from the brand-name manufacturer, regardless of whether the prescription is ultimately filled with the generic version of the drug.⁷³

Although this recent trend toward shifting liability is still the minority view, it is garnering much criticism.⁷⁴ The major complaint is that brand-name manufacturers invest in the research and testing to develop the new drug, in addition to bearing the costs of promoting and informing healthcare providers about it; whereas generic manufacturers “sweep into the market after the brand-name drug’s patent protection has expired and reap profits from selling the drug without having incurred any of the costs of its development and promotion.”⁷⁵ Brand-name manufacturers believe those factors make it unfair for courts to assign them liability for injuries resulting from the generic version of their drug.⁷⁶ The FDA’s proposal, however, would end any possibility of taking this minority trend mainstream, as its passage would eliminate any uncertainty regarding who should be held liable.⁷⁷ Generic drug manufacturers would be

71. See *Conte v. Wyeth, Inc.*, 85 Cal. Rptr. 3d 299, 320-21 (Ct. App. 2008) (holding brand-name manufacturers’ duty to use due care providing warnings extends to generic equivalent). The *Conte* court stated the risk of harm to a patient who takes the generic drug is foreseeable to the brand-name manufacturer; thus, the brand-name manufacturer should be liable. See *id.* at 321.

72. See *Dolin v. SmithKline Beecham Corp.*, 62 F. Supp. 3d 705, 715 (N.D. Ill. 2014) (holding brand-name manufacturer owes duty because sufficient relationship with party injured from generic drug); *Kellogg v. Wyeth*, 762 F. Supp. 2d 694, 708-09 (D. Vt. 2010) (refusing to limit brand-name manufacturer’s duty if pharmacist fills prescription with generic equivalent); *Wyeth, Inc. v. Weeks*, 159 So. 3d 649, 704 (Ala. 2014) (declaring brand-name manufacturer potentially responsible for injuries caused by ingesting generic drug); see also Anne Bucher, *Ala. Supreme Court Holds Pfizer Can Be Liable for Generic Drug Claims*, TOP CLASS ACTIONS (Aug. 18, 2014), <http://topclassactions.com/lawsuit-settlements/lawsuit-news/37695-ala-supreme-court-holds-pfizer-can-liable-generic-drug-claims/> [<http://perma.cc/T653-XEFD>] (discussing *Wyeth, Inc. v. Weeks*, which allowed suit for damages generic drug caused). Under the theory of innovator liability, brand-name drug manufacturers are responsible for creating and monitoring both their labels and the generic version’s labels, which means they can be liable for any injuries caused by the labeling of either version of the drug. See *Chatman v. Pfizer, Inc.*, 960 F. Supp. 2d 641, 651 (S.D. Miss. 2013).

73. See *Kellogg*, 762 F. Supp. 2d at 709 (holding it reasonably foreseeable physicians rely on brand-name warnings); Victor E. Schwartz et al., *Warning: Shifting Liability to Manufacturers of Brand-Name Medicines When the Harm Was Allegedly Caused by Generic Drugs Has Severe Side Effects*, 81 FORDHAM L. REV. 1835, 1852 (2013) (explaining brand-name manufacturer held liable for injury from generic drug in *Kellogg*).

74. See Allen Rostron, *Prescription for Fairness: A New Approach to Tort Liability of Brand-Name and Generic Drug Manufacturers*, 60 DUKE L.J. 1123, 1175 (2011) (outlining critical arguments after *Conte* decision).

75. *Id.*

76. See *id.* at 1175-77 (arguing criticism of unfairness unwarranted because brand-name manufacturer not subject to strict liability).

77. See Julia M. Rafferty & Alex L. Rubenstein, *Proposed FDA Rule Could Bring Failure-To-Warn Liability*, LAW360 (Jan. 23, 2014), <http://www.law360.com/articles/503175/proposed-fda-rule-could-bring-failure-to-warn-liability> [<http://perma.cc/LFQ7-7WXZ>] (explaining new rule gives generic manufacturers

unilaterally responsible for updating their drugs' warning labels, so the protection granted to generic manufacturers in *PLIVA* would no longer apply if the proposal is accepted.⁷⁸

III. ANALYSIS

A. *Curing Confusion or Prescribing Chaos?*

The FDA's proposed law has the potential to impose extreme harm on the pharmaceutical industry.⁷⁹ Increased liability risks may force generic drug manufacturers to exit markets, leaving expensive brand-name drugs as consumers' only option.⁸⁰ Even if those generic drug manufacturers remain in the industry, the supply of generic drugs may decrease because consumers will be confronted with different labels for the same medication and may instinctively trust the brand-name drug over the generic counterpart.⁸¹ This reversion to brand-name drugs will increase healthcare costs for both manufacturers and consumers, thus severely damaging the pharmaceutical industry.⁸² A report by Matrix Global Advisors predicts the cost of generic drugs could increase by four billion dollars a year if the FDA enacts this regulation.⁸³ Consumers will be responsible for that increased cost to manufacturers, and, accordingly, they may no longer have the option to buy cheaper generic drugs, and may instead opt into paying similar prices for the brand-name version of the drug.⁸⁴ The proposed rule may also lead to fewer

"independent right" to update information).

78. See *id.* (emphasizing *PLIVA* decision relied on generic manufacturers having no ability to change labels independently). The Hatch-Waxman Act preempts any state failure-to-warn claims against generic drug manufacturers because the federal law prohibits them from making any unilateral changes to their warning labels. See *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2578 (2011). Commentators claim "the proposed FDA rule completely undercuts the underlying reasoning in *Mensing*." Rafferty & Rubenstein, *supra* note 77.

79. See Letter from Israel & Bishop, *supra* note 61 (claiming if proposal effective, generic drug supply will drop); see also Letter from Members of Cong., *supra* note 61 (warning increased exposure to tort claims may increase generic drug costs).

80. See BRILL, *supra* note 61, at 6 (explaining generic manufacturers may leave market due to fear of liability).

81. See Letter from Israel & Bishop, *supra* note 61 (stating FDA website emphasizing identical labeling encourages consumers to use generic drugs).

82. See *id.* (stressing importance of using generic drugs in keeping costs low).

83. See BRILL, *supra* note 61, at 1 (claiming proposal would cost generic drug manufacturers billions because of product liability claims); see also Silverman, *supra* note 15 (explaining generic manufacturers fear new ways to appear negligent). If the proposal takes effect and generic drug manufacturers become responsible for the content of their own labels, those manufacturers would have to conduct their own studies, instead of relying on preexisting studies conducted by brand-name manufacturers, which would be costly. See Croom, *supra* note 61, at 29.

84. See Letter from Members of Cong., *supra* note 61 (arguing proposed law could cost manufacturers billions and increase price of drugs for consumers); Letter from Minority Orgs., *supra* note 61 (warning proposal could cause consumers to "shun life-saving generic drugs completely"). Currently, generic drugs dominate the market in the United States, as they account for more than eighty percent of prescriptions filled. See Woodcock Statement, *supra* note 60. Generic drugs also cost eighty to eighty-five percent less than brand-

generic drug manufacturers entering the market, as well as manufacturers withdrawing drugs from certain markets due to increased cost and liability concerns.⁸⁵

If passed, the proposal will also have drastic legal consequences for generic drug manufacturers.⁸⁶ The proposal subjects generic drug manufacturers to potential liability for failure-to-warn claims that they were previously protected against because they were unable to unilaterally change the safety information on their warning labels.⁸⁷ The increase in lawsuits and the expenses that result will force generic drug manufacturers to raise drug prices, withdraw some of their drugs, or decide not to introduce new, affordable versions of brand-name drugs into the market.⁸⁸ In addition to increasing the likelihood of failure-to-warn claims, this proposal will also increase generic drug manufacturers' exposure to product liability claims.⁸⁹ Generic drug manufacturers will thus have to "increase their vigilance in obtaining and disseminating new safety information" and prepare to defend against the influx of product liability claims that will inevitably result.⁹⁰ The litigation and settlement of these new potential tort and product liability claims, coupled with taking measures to

name drugs. See U.S. FOOD AND DRUG ADMIN., *supra* note 2. Every year, generic drugs increasingly save federal and state programs and taxpayers billions of dollars. See GENERIC PHARM. ASS'N, *supra* note 63, at 1.

85. See GPHA OVERVIEW AND ASSESSMENT, *supra* note 62, at 4 (stating concerns over future of generic drug alternatives). The proposal will likely force some generic drug manufacturers out of the United States. See *id.* The proposal may not only impact the availability of inexpensive generic drugs, but it may also increasingly contribute to situations where life-saving drugs are either in short supply or not available at all. See *id.*

86. See *Proposed Rule from FDA*, *supra* note 68 (suggesting proposal may eliminate preemption of failure-to-warn claims against generic drugs); see also Blazer, *supra* note 57 (stating proposal will increase exposure of generic drug manufacturers to failure-to-warn claims); GPHA OVERVIEW AND ASSESSMENT, *supra* note 62, at 4 (arguing risk of litigation for generic drug manufacturers may cause shortage of necessary drugs).

87. See Blazer, *supra* note 57 (explaining lack of control barring generics from failure-to-warn claims nonissue under proposal); Rafferty & Rubenstein, *supra* note 77 (discussing ramifications of proposal on PLIVA and generics' new exposure to failure-to-warn claims); see also PLIVA, Inc. v. Mensing, 131 S. Ct. 2567, 2578, 2581 (2011) (holding federal law preempted state law's imposed duty to update warning labels); Wyeth, Inc. v. Weeks, 159 So. 3d 649, 677 (Ala. 2014) (explaining federal requirement of identical labels preempted failure-to-warn claims against generic manufacturers).

88. See Letter from Minority Orgs., *supra* note 61 (criticizing proposal and its potential effects on generic drugs' affordability); see also Rafferty & Rubenstein, *supra* note 77 (explaining proposal's potential to expose generic manufacturers to more lawsuits and increase cost of drugs).

89. See BRILL, *supra* note 61, at 2 (expressing increased product liability exposure will greatly increase healthcare costs). To account for increased product liability costs, public and private health insurance costs will also increase. See *id.* Exposure to product liability claims will increase generic drug prices because: generic manufacturers will have increased costs resulting from higher insurance premiums and self-insurance costs; generic manufacturers may remove themselves from certain markets they estimate to have the greatest liability risks; insurance companies may leave the market because of increased risks, requiring generic manufacturers to have higher premiums and increase the costs of their drugs to offset these expenses; and generic manufacturers would take on the expensive costs of repeating brand-name manufacturers' testing and procedures to monitor the safety of their drugs. See *id.* at 6.

90. Rafferty & Rubenstein, *supra* note 77.

reduce liability risks, will directly correlate to increased generic drug costs.⁹¹ Over time, competition in the market will suffer because generic drug manufacturers will withdraw drugs as a result of increased exposure to lawsuits, which will also influence the upward shift in prices.⁹²

B. Potential Side Effects for Healthcare Professionals and Patients

The proposal, however, will most negatively affect healthcare professionals and patients.⁹³ Instead of enhancing drug safety, the proposal will lead to confusion because it allows equivalent drugs to have different warning labels.⁹⁴ The duty of sameness created by the Hatch-Waxman Act led to the success of generic drugs for the past thirty years, and the FDA's proposal severely undermines that principal.⁹⁵ Even internally, within the FDA Office of Generic Drugs, the former Deputy Director expressed concerns with the proposal, stating, "Disregarding decades of regulatory stability in this way will create unwarranted confusion, raises patient safety concerns and threatens the system that created thousands of affordable options for consumers."⁹⁶ In a recent study among healthcare professionals, seventy-six percent believe multiple labels for the same drug would cause patient confusion, and eighty-eight percent think multiple labels would confuse doctors themselves.⁹⁷ Generic and brand-name drug labels should be identical to maximize risk and benefit awareness among providers and patients, regardless of which manufacturer appears on the bottle.⁹⁸ To combat this problem, the FDA's proposal includes

91. See GOTTlieb ET AL., *supra* note 63, at 4 (indicating generic manufacturers' increased spending on product liability insurance substantially increases consumer spending on generics).

92. See *id.* (explaining competition lowers prices, and proposal would likely reduce competition in generic drug market).

93. See Letter from Israel & Bishop, *supra* note 61 (stating healthcare providers and pharmacists concerned with proposal's negative impact on patient care).

94. See GPHA OVERVIEW AND ASSESSMENT, *supra* note 62, at 2 (explaining proposal contrary to longstanding emphasis on consistency and will cause confusion); see also Letter from Spangler, *supra* note 61 (noting potential for confusion due to multiple labels heightened with over-the-counter drugs).

95. See GPhA to Cong., *supra* note 62 (relaying concerns from Gordon Johnston, former Deputy Director, FDA Office of Generic Drugs).

96. *Id.* (emphasizing label consistency helps providers and patients feel comfortable with risks of drug).

97. See FAIRLEIGH DICKINSON UNIV., *supra* note 62, at 2, 9, 12 (detailing findings from telephone survey of 450 physicians, physician assistants, and pharmacists); see also Letter from Minority Orgs., *supra* note 61 (stating fifty-three percent of surveyed healthcare professionals surveyed find multiple labels "very confusing"). In that same study, sixty percent of prescribers believe the proposal will impact their willingness to recommend generic drugs to their patients. See FAIRLEIGH DICKINSON UNIV., *supra* note 62, at 15. In addition, seventy-one percent believe the proposal will impact the amount of time they will need to spend looking at their patients' history and cross referencing it with different warning labels. See *id.* at 10. Moreover, seventy-four percent think the proposal will impact the amount of time needed for researching all of the label differences. See *id.* at 11. Perhaps the most concerning statistic: sixty-eight percent of healthcare professionals think they will not have the time necessary to keep informed of each labeling change. See *id.* at 13.

98. See Letter from Members of Cong., *supra* note 61 (emphasizing label consistency helps providers and patients feel comfortable with risks of drug).

creating a website that will be updated as new safety information is discovered, but such a solution inadequately eases confusion arising from differing labels.⁹⁹

In addition to the mass confusion the proposal will likely create, the proposal will also negatively affect patient safety because it requires generic drug manufacturers to distribute safety information that the FDA has neither reviewed nor approved.¹⁰⁰ This information may not be scientifically accurate, which could lead to healthcare professionals unintentionally prescribing medications based on false or misleading risks and benefits.¹⁰¹ Furthermore, the proposal requires generic drug manufacturers to submit an application for proposed label changes while the FDA assesses the changes, allowing unapproved labels to enter the market in the interim.¹⁰²

Aside from confusing consumers and prescribers alike, the proposal also harms patients because it can place life-saving drugs out of financial reach.¹⁰³ Since 2004, generic drugs saved the health system nearly \$1.5 trillion, and between 2012 and 2013, there was a fourteen percent increase in cost savings.¹⁰⁴ Those billions of dollars saved are attributable to the Hatch-Waxman Act, which encouraged developing generic versions of brand-name drugs.¹⁰⁵ These savings, however, may experience an abrupt halt if this proposal is enacted because it will greatly increase costs for generic drug manufacturers.¹⁰⁶ Cost is a major factor for ensuring patients comply with

99. See Sampson & Bradshaw, *supra* note 38, at 8 (asserting website will not ease concerns about generic labels differing from brand name). The proposed website is irrelevant for over-the-counter drugs because consumers rely almost exclusively on warning labels at the time of purchase. See Letter from Spangler, *supra* note 61. Consumers select over-the-counter drugs on their own, without the assistance of a physician or pharmacist, so a website with safety updates will not be helpful when consumers are in a pharmacy aisle trying to determine which drug to purchase. See *id.*

100. See Sampson & Bradshaw, *supra* note 38, at 7-8 (explaining generic manufacturers have limited safety information). Generic drug manufacturers do not have access to safety information gathered by brand-name manufacturers or other generic manufacturers, and if the proposal is adopted, generic manufacturers could use information on their labels that the FDA will later deem scientifically inaccurate. See *id.*

101. See *id.* at 8 (arguing scientifically inaccurate safety information can weaken representation of benefits and risks prescribers rely on).

102. See Letter from Members of Cong., *supra* note 61 (explaining process generic drug manufacturers must follow to update labels under proposed rule); see also GPhA OVERVIEW AND ASSESSMENT, *supra* note 62, at 9 (asserting GPhA does not support process of forcing submission of proposed changes before FDA approval). The proposal would require generic drug manufacturers to update their drug labels as soon as they acquire new safety information and submit a CBE-o supplement to the FDA for review. See Rafferty & Rubenstein, *supra* note 77.

103. See Letter from Minority Orgs., *supra* note 61 (elucidating proposal's increased expenses for generic drug manufacturers may limit ability to provide affordable drugs); see also GOTTLIEB ET AL., *supra* note 63, at 4 (suggesting large impact on affordability of generic drugs).

104. See GENERIC PHARM. ASS'N, *supra* note 63, at 1 (announcing generic cost savings of \$239 billion for 2013). New generic drugs that entered the market in 2013 saved the healthcare system \$140 billion. See *id.* at 2.

105. See *id.* at 3 (maintaining Hatch-Waxman Act responsible for boom in drug development and decreased drug prices).

106. See Letter from Members of Cong., *supra* note 61 (stating proposal inconsistent with sameness requirement of Hatch-Waxman Act). The proposal allows the same drug to have multiple warning labels,

proper medication use; more than one in ten seniors in the United States reported not using required medications as often as instructed because of the cost.¹⁰⁷ The subsequent nonadherence to proper medication will negatively affect patients' health because that cost will deter them from regularly procuring the prescriptions they need.¹⁰⁸

C. The FDA's Proposal Fails To Follow Instructions

Amidst concerns over the proposal's impact, there is also a question of legality and whether the FDA has the authority to implement these new regulations.¹⁰⁹ Legal experts argue that the Hatch-Waxman Act does not allow for any drastic changes to its sameness requirement, like the ones proposed.¹¹⁰ The Hatch-Waxman Act expressly prohibits the exact process that the FDA's proposal attempts to utilize, leading experts to question the FDA's blatant disregard for the federal law's requirements.¹¹¹ Aside from contradicting the existing Hatch-Waxman Act, which controls the process for implementing warning label changes, the proposal also seeks to counteract congressional

which undermines the Hatch-Waxman Act's purpose of ensuring safe and effective generic drugs. *See id.* The proposal would inevitably increase generic drug prices, which undermines the Hatch-Waxman Act's adept balance of incentivizing new drug development while also encouraging competition. *See id.* (explaining proposal would result in increased prices for generics because of costly and duplicative testing).

107. *See* GPHA OVERVIEW AND ASSESSMENT, *supra* note 62, at 5 (declaring medication nonadherence costs healthcare system \$290 billion). Improper use of medication negatively impacts the healthcare system because misuse leads to costly health complications, worsening of symptoms, and preventable utilization. *See id.* Generic drugs increase patients' compliance with prescription orders given their accessibility and affordability. *See* GENERIC PHARM. ASS'N, *supra* note 38, at 3. In addition to the financial impact of nonadherence, it also leads to 125,000 deaths per year. *See id.*

108. *See* GPHA OVERVIEW AND ASSESSMENT, *supra* note 62, at 5 (stressing noncompliance with medications leads to lower quality of life). Drug cost is often the reason why patients stop taking medication that could save their lives. *See* GENERIC PHARM. ASS'N, *supra* note 38, at 3. Patient nonadherence to prescriptions costs the healthcare system close to \$300 billion per year because it leads to extra doctor visits, emergency room visits, and hospitalizations. *See id.*

109. *See* GOTTLIEB ET AL., *supra* note 63, at 3 (expressing concerns over legality of FDA's actions because in direct conflict with Hatch-Waxman Act).

110. *See id.* (stating FDA cited no evidence Supreme Court decisions gave it authority for proposed changes); *Experts*, *supra* note 64 (listing legal opinions stating FDA does not have authority to contradict Hatch-Waxman Act); *see also* GPHA OVERVIEW AND ASSESSMENT, *supra* note 62, at 8 (emphasizing Supreme Court stated Hatch-Waxman Act does not allow generics to make labeling changes).

111. *See* *Generic Drug Industry Threatens FDA*, *supra* note 64 (offering legal expert opinions of illegality of straying from Hatch-Waxman Act's sameness requirement); *see also* Sampson & Bradshaw, *supra* note 38, at 7 (arguing proposal contrary to plain language of federal law). The current federal law provides that a generic drug must have the same labeling that was approved for the brand-name version of the drug, which is a sentiment the FDA has continuously conveyed. *See* Sampson & Bradshaw, *supra* note 38, at 7. Congress also expressly provided that it wants brand-name and generic drug manufacturers to have different labeling duties. *See id.* The congressional intent in enacting the Hatch-Waxman Act was to make brand-name drug manufacturers responsible for maintaining the accuracy and adequacy of drug labels, while generic drug manufacturers would be responsible for maintaining the same label as the brand-name version of the drug. *See id.* Allowing generic drug manufacturers to have a duty similar to brand-name manufacturers, where they are responsible for updating their warning labels independently, undermines congressional intent and exceeds the FDA's authority. *See id.*

intent by unhinging the delicate balance established between new drug innovation and cheaper generic drug alternatives.¹¹² The FDA argues its authority to extend the process of updating labels to generic drug manufacturers stems from its authority to create the original labeling process for brand-name drug manufacturers.¹¹³ The FDA does not, however, state where it gets the authority to implement a regulation that disregards a federal statute.¹¹⁴ The GPhA indicated it will sue the FDA if the proposal is finalized because the proposal contradicts the plain language and the Supreme Court's interpretation of the Hatch-Waxman Act.¹¹⁵

D. Adverse Consequences for the Healthcare System

The proposal negatively impacts the healthcare system, while providing few benefits to public health.¹¹⁶ The FDA purports to ensure warning labels reflect the most recent safety information, but this proposal fails to provide an effective way to achieve that end.¹¹⁷ Most generic drug manufacturers do not update their labels to incorporate newly discovered safety risks, but rather manufacturers update their labels to add well-known side effects that are deemed important enough to require a more prominent place on warning labels.¹¹⁸ While the proposal may provide some new safety information to the public, the label changes will most likely include unnecessary and clinically irrelevant risks purely to quell generic drug manufacturers' fears of failure-to-warn liability.¹¹⁹ Exaggerating the risks and overwarning can also serve to dissuade physicians from prescribing an otherwise-beneficial drug.¹²⁰

112. See Sampson & Bradshaw, *supra* note 38, at 7 (asserting FDA's proposal contrary to both federal law and legislative intent).

113. See *id.* (stating FDA believes it has proper authority to enact proposal).

114. See *id.* (asserting no authority grants FDA ability to create regulatory exception to statutory requirement).

115. See *Generic Drug Industry Threatens FDA*, *supra* note 64 (quoting GPhA's President, Ralph Neas, stating, "this proposed rule exceeds FDA's statutory authority"). The GPhA will challenge the legality of the proposal if the FDA proceeds with a more finalized step because "[s]everal maxims of statutory construction would seem to preclude the FDA from doing what it seeks to do here." *Id.* The proposal threatens to invalidate the Supreme Court's decision in *PLIVA* and negate the Hatch-Waxman Act—the controlling federal law for over thirty years. See Overley, *supra* note 64.

116. See GOTTIEB ET AL., *supra* note 63, at 5 (arguing proposal undermines public health benefits provided by generic drugs).

117. See *id.* at 2 (claiming new policy as "misguided and unmanageable"). Instead of focusing on keeping generic warning labels up to date, the FDA wants to undercut the Supreme Court decisions that shield generic drug manufacturers from tort liability in failure-to-warn and products liability claims. See *id.*

118. See *id.* (stating most label changes reflect new clinical norms as opposed to newly discovered risks). Generic drug warning labels are often changed because new therapies develop that provide safer treatment alternatives for certain medical conditions. See *id.*

119. See Traynor, *supra* note 59 (restating concerns proposal will lead to overwarning and create "substantial confusion").

120. See BRILL, *supra* note 61, at 6 (stressing overwarning weakens effectiveness of drug labels); Sampson & Bradshaw, *supra* note 38, at 8 (asserting exaggerating risks on warning labels may discourage

Overwarning serves only to confuse patients and prescribers with an abundance of unessential information, thereby negating the parity between generic and brand-name drugs that has been successful since the Hatch-Waxman Act's passage in 1984.¹²¹

IV. CONCLUSION

The proposal's inherent objective—to allow generic drug manufacturers to change their warning labels temporarily—negatively impacts the industry and serves as a clear indication that the FDA should reject the proposal. Although the FDA's reason for proposing the changes is respectable and provides a strong argument for reform, the current proposal is far from an appropriate solution. The negative consequences that would inevitably result from the proposed regulations far outweigh the possible benefits. Although the new regulations would likely result in faster distribution of new drug safety information, the increased litigation and costs to the healthcare system would overshadow the proposal's positive impact.

The FDA should continue to prioritize disseminating safety information for pharmaceuticals, as the current system is far from perfect. These proposed regulations, however, fail to resolve the system's defects and perhaps worsen it by putting life-saving medications out of reach. In an attempt to tip the scales to create a system in which the FDA and brand-name manufacturers do not bear sole responsibility for warning label disclosures, the FDA simultaneously deemphasized public safety issues. The agency prioritized its own needs and desires over those for whom the administration was created. The FDA should continue to strive to strike a better balance between disseminating new safety information, preserving the successful aspects of the sameness requirement, and maintaining the availability and affordability of generic drugs.

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prescription of drug with potentially beneficial effects).

121. See GOTTlieb ET AL., *supra* note 63, at 4 (predicting proposal will lead to confusing and conflicting warning labels for same drugs).